



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration  
College Park, MD 20740

JUN 21 2004

Ms. Gladys Valencia  
Director  
HerbsForever, Inc.  
501 S. Harvard Boulevard, #2  
Los Angeles, California 90020

Dear Ms. Valencia:

This is in response to your letter to the Food and Drug Administration (FDA), dated May 11, 2004, pursuant to 21 U.S.C. 343(r)(6) (section 403(r)(6) of the Federal Food, Drug, and Cosmetic Act (the Act)). Your submission states that HerbsForever, Inc. is marketing the products **Masha Vishgarba Oil** and **Maha Narayan** for external or topical uses. The products are described as "For external use only" (both products), as a "Natural Herbal Joint and Muscle Vatta Massage oil" (Masha Vishgarba Oil), and "Vatta Massage Oil" (Maha Narayan).

These products do not appear to meet the statutory definition of a dietary supplement contained in 21 U.S.C. 321(ff), and therefore, can not be marketed as dietary supplements. We explain the basis for our opinion below.

The term "dietary supplement" is defined in 21 U.S.C. 321(ff). 21 U.S.C. 321(ff) provides that the term means a product (other than tobacco) intended to supplement the diet that bears or contains a vitamin, a mineral, an herb or other botanical, an amino acid, a dietary substance for use by man to supplement the diet by increasing the total dietary intake, or a concentrate, metabolite, constituent, extract, or combination of any of the above ingredients. 21 U.S.C. 321(ff) further states that dietary supplements are intended for ingestion in a form described in 21 U.S.C. 350(c)(1)(B)(i) or in compliance with 21 U.S.C. 350(c)(1)(B)(ii), are not represented as conventional food or as a sole item of a meal or the diet, and are labeled as a dietary supplement.

An article that is applied externally to the skin is not "intended for ingestion." As stated above, the definition of dietary supplement in 21 U.S.C. 321(ff) states that a dietary supplement is a product "intended for ingestion." The term "ingestion" has been addressed by the court in United States v. Ten Cartons, Ener-B Nasal Gel, 888 F. Supp. 381, 393-94 (E.D.N.Y.), aff'd, 72 F.3d 285 (2d Cir. 1995), which states:

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The ordinary and plain meaning of the term “ingestion” means to take into the stomach and gastrointestinal tract by means of enteral administration. See Stedman’s Medical Dictionary (4th Lawyer’s Ed. 1976) (defining ingestion as the “introduction of food and drink into the stomach.”); Webster’s Third New International Dictionary (1976) (defining ingestion as “the taking of material (as food) into the digestive system.”)...

The interpretation of the term “ingestion” to mean enteral administration into the stomach and gastrointestinal tract is also supported by the language of the statutory sections immediately preceding and following section 350(c)(1)(B)(ii). Section 350(c)(1)(B)(i) states that the vitamin must be intended for ingestion in tablet, capsule or liquid form. Each of these forms denotes a method of ingestion that involves swallowing into the stomach. Section 350(c)(2) states that a food is intended for ingestion in liquid form under section 350(c)(1)(B)(i) “only if it is formulated in a fluid carrier and is intended for ingestion in daily quantities measured in drops or similar small units of measure.” This elaboration of “liquid form” also denotes ingestion by swallowing the fluid.

Therefore, because the term “ingestion” means introduced into the gastrointestinal tract, products that are intended to be used topically are not subject to regulation as dietary supplements because they are not “intended for ingestion” and are drugs under 21 U.S.C. 321(g)(1)(C) because they are articles (other than food) intended to affect the structure or function of the body.

Please contact us if we may be of further assistance.

Sincerely yours,

A handwritten signature in black ink, appearing to read 'SJW', with a stylized flourish at the end.

Susan J. Walker, M.D.  
Director  
Division of Dietary Supplement Programs  
Office of Nutritional Products, Labeling  
and Dietary Supplements  
Center for Food Safety  
and Applied Nutrition

Copies:

FDA, Center for Drug Evaluation and Research, Office of Compliance, HFD-300  
FDA, Office of the Associate Commissioner for Regulatory Affairs, Office of  
Enforcement, HFC-200  
FDA, Los Angeles District Office, Compliance Branch, HFR-PA240

# Herbsforever, Inc.

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May 11, 2004



Dr. Elizabeth Yetley  
Office of Special Nutrition (HFS-450)  
Center of Food Safety and Applied Nutrition  
Food and Drug Administration  
200 C Street S.W.  
Washington, DC 20204

Re: Notification of Product Claims

Dear Dr. Yetley:

This letter serves as notification of the nutrition support labeling statements being made by our company in connection with our line of dietary nutritional supplements. A list of the products and their respective nutritional support statements and ingredients are listed in the attached Exhibit "A".

Herbsforever certifies that the information contained in this notice is complete and accurate, and the company maintains documentation to substantiate that its product claims are truthful and not misleading.

If you have any questions, please feel free to contact me and I will do my best to answer your questions.

A handwritten signature in cursive script that reads "Gladys Valencia".

Gladys Valencia  
Director  
Herbsforever, Inc.

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## **Maha Vishgarba Oil**

**For external use only**

**Natural Herbal Joint  
and Muscle Vatta Massage oil**

**Maha Vish Garba oil:** Recommended for old Vatta and Kapha dosha conditions as per Ayurvedic theory of Tridosha: Vatta (air), Pitta (fire), Kapha (water).

**Ingredients:** Sesame oil, Datura alba, Vitex Negundo, Citrullus colocynthis, Boerhaavia diffusa, Ricinus communis, Withania somnifera, Plumrango geylanica, Moringa oleifera, Solanum nigrum, Solanum xanthocarpum, Azardica indicus, Melia azedarach, Callicarpa lanata, Aegle marmelos, Oroxylum indicum, Gmelina arobrea, Stereospermum suaveolens, Premna integrifolia, Desmodium gangeticum, Uria picta, Solanum indicum, Tribulus terrestris, Asparagus racemosus, Nerium odorum, Ichnocarpus frutescens, Sphaeranthus indicus, verbascifolium, Euphorbia antiquorum, Calotropis Gigantea, Leele Aequata, Achyranthes Aspera, Sida cordifolia, Abutilon indicum, Spinosa, Sida cordifolia big, Litsea Chinensis, Latifolium, Paederia fotida, Ginger, Piper nigrum, Piper longum, Nuxvomica, Pluchea lancolata, Costus, Aconitum Balfourii, Cyperus rotundus, Cedrus deodara, Lagenandra, Barilla, Rock salt, Unaqua Sodium chloride, Pottasium nitrate, Sodii muras, Copper Sulphate, Myrica Nagi, Cissampelos Pareira, Premna herbacea, Ammonium chloride, Boliospermum montanum, Oryza sativa, Cumin, Citrullus colocynthis.

## **Maha Narayan**

**Vatta Massage oil**

**For external use only**

This oil is recommended for high Vatta conditions as per Ayurvedic theory of Tridosha.

**Ingredients:** Sesame seed oil, Cow milk, Eucalyptus oil, Aegle marmelos, Withania somnifera, Solanum indicum, Tribulus terrestris, Oroxylum indicum, Sida cordifolia, Erythrina indica, Solanum xanthocarpum, Boerhaavia diffusa, Abutilon indicum, Premna integrifolia, Paederia foetida, Stereospermum suaveolens, Asparagus racemosus, Pluchea lanceolata, Leptadenia reticulata, Cedrus deodara, Sarcostigma kleinii, Hedysarum gangeticum, Uria picta, Phaseolus trilobus, Teramnus labialis, Mesua ferrea, Rock salt, Curcuma Zedoaria, Curcuma longa, Terminalia chebula, Boswellia, Inula racemosa, Tacca aspera, Cardamomum, Rubia cordifolia, Glycyrrhiza glabra, Valeriana wallichii, Cyperus rotundus, Cinnamomum obtusifolium, Eclipta alba, Gymnema lactiferum, Clove, Butea frondosa, Alstonia scholaris, Camphor, Cinnamon, Crocus sativus, Nymphaea stellata, Ipomoea digitata, Ginger, Hedychium spicatum, Centella asiatica.

## **KANCHNARA GUGGULU**

Kanchnara Guggulu is traditionally used in Ayurveda for deep-seated toxins in the tissues. Supports healthy Glandular functions. Helps to maintain healthy metabolism & helps to remove toxins from the system. \*\*